



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2016-0573; FRL-9975-07]

Tetraconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of tetraconazole in or on multiple commodities which are identified and discussed later in this document. Isagro S.p.A (d/b/a Isagro USA, Inc.) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2016-0573, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703)

305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2016-0573 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2016-0573, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of December 20, 2016 (81 FR 92758) (FRL-9956-04), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6F8507) by Isagro S.p.A (d/b/a Isagro USA, Inc.), 430 Davis Drive, Suite 240, Morrisville, NC 27560. The petition requested that 40 CFR 180.557 be amended by establishing tolerances for residues of the fungicide tetraconazole, 1-[2-(2,4-dichlorophenyl)-3-(1,1,2,2-tetrafluoroethoxy)propyl]-1H-1,2,4-triazole, in or on barley at 0.3 parts per million (ppm); crop group 16, forage, fodder, and straw of cereal grains group (except corn) at 8.0 ppm; dried shelled pea and bean (except soybean) subgroup 6C, hay at 8.0 ppm; dried shelled pea and bean (except soybean) subgroup 6C, seed at 0.15 ppm; dried shelled pea and bean (except soybean) subgroup 6C, vine at 2.0 ppm; rapeseed crop subgroup 20A at 0.9 ppm; and wheat at 0.1 ppm. That document referenced a summary of the petition prepared by Isagro S.p.A (d/b/a Isagro USA, Inc., the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA is establishing tolerances that vary slightly from what the petitioner requested. The reason for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration

to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for tetraconazole including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with tetraconazole follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The liver and kidney are the primary target organs of tetraconazole in all species in oral toxicity studies of subchronic and chronic durations. Following long-term oral exposure, tetraconazole caused liver tumors in mice in both sexes. In the acute neurotoxicity study, loss of motor activity in both sexes, and clinical signs including hunched posture, decreased defecation, and/or red or yellow material on various body surfaces were observed in females. There was no evidence of immunotoxicity or neurotoxicity following subchronic exposure. There were no systemic effects observed in the 21-day dermal toxicity study up to the highest dose tested. Tetraconazole did not show evidence of mutagenicity in *in vitro* or *in vivo* studies.

Oral rat and rabbit prenatal developmental studies showed no evidence for increased quantitative susceptibility *in utero*. Developmental effects (increased incidences of

supernumerary ribs, and hydroureter and hydronephrosis) were seen in the presence of maternal effects in rats (decreased body weight gain, and food consumption and increased water intake, and increased liver and kidney weights), while no developmental effects were seen in rabbits. A 2-generation rat reproduction study also revealed no evidence for increased quantitative susceptibility in offspring. Decreased litter and mean pup weights and increased liver weights were noted in offspring at a dose higher than that which caused mortality in adult females. Effects in parental animals that survived the duration of the study were consistent with other studies in the database. In contrast to the oral studies where the most sensitive effects were in the liver and kidney, inhalation exposure of tetraconazole to rats resulted in portal-of-entry effects, including squamous cell metaplasia of the laryngeal mucous, mononuclear cell infiltration, goblet cell hyperplasia, hypertrophy of the nasal cavity and nasopharyngeal duct, and follicular hypertrophy of the thyroid in males. At the highest concentration tested, there were treatment-related increases in absolute lung weights in both sexes.

Although liver tumors were observed in mice in both sexes in a mouse carcinogenicity study, the agency has classified tetraconazole as “Not likely to be carcinogenic to humans at levels that do not cause increased cell proliferation in the liver.” This classification is supported by an *in vivo* cancer mode-of-action study in mice, demonstrating that cancer risk is linked to increased cell proliferation in the liver. Because the current reference dose (RfD) of 0.0073 mg/kg/day is below the level at which increased cell proliferation occurs in the liver, it would be protective of any liver effects caused by tetraconazole in the mouse carcinogenicity or MoA studies at higher doses. Quantification of carcinogenic potential is not required.

Tetraconazole was categorized as having low acute toxicity via the oral, dermal, and inhalation routes (Toxicity Categories III-IV). It is not a dermal irritant or a dermal sensitizer. It is considered a slight eye irritant.

Specific information on the studies received and the nature of the adverse effects caused by tetraconazole as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies

can be found at <http://www.regulations.gov> in document “Human Health Risk Assessment for the Section 3 Registration for Application to add Crop Group 6C, Dried Shelled Pea and Bean (except Soybean) Subgroup, Barley, Canola, Wheat, and Crop Group 16, Forage Fodder, and Straw of Cereal Grains Group (except corn)” in docket ID number EPA-HQ-OPP-2016-0573.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general

principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for tetraconazole used for human risk assessment is discussed in Unit B of the final rule published in the **Federal Register** of January 10, 2017 (82 FR 2900) (FRL-9955–74).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to tetraconazole, EPA considered exposure under the petitioned-for tolerances as well as all existing tetraconazole tolerances in 40 CFR 180.557. EPA assessed dietary exposures from tetraconazole in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for tetraconazole. In estimating acute dietary exposure, EPA used food consumption information from the 2003-2008 United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA used tolerance-level residues and 100 percent crop treated (PCT) estimates.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA NHANES/WWEIA (2003-2008). As to residue levels in food, EPA utilized residue data from field trials and feeding studies to obtain average residues and assumed the PCT estimates provided in Unit III.C.1.iv. Empirically derived processing factors were used in these assessments when available.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that tetraconazole has been classified as “Not likely to be carcinogenic to humans at levels that do not cause increased cell proliferation in the liver.” Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information*. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

For the chronic dietary exposure assessment, the Agency used the following PCT estimates for existing uses as follows:

Corn, 1%; grapes, 5%; peanuts, 1%; strawberries, 2.5%; sugar beet, 25%; and soybean, 2.5%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6-7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than 2.5% or 1%. In those cases, the Agency uses 2.5% or 1%, respectively, as the average PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, unless the maximum PCT value is estimated at less than 2.5%, in which case the Agency uses 2.5% as the maximum PCT value in the analysis.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not

understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which tetraconazole may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for tetraconazole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of tetraconazole. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of tetraconazole for acute exposures are estimated to be 11 parts per billion (ppb) for surface water and 120 ppb for ground water. The estimated EDWCs of tetraconazole for chronic exposures for non-cancer assessments are estimated to be 5.5 ppb for surface water and 118 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 120 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 118 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Tetraconazole is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

Tetraconazole is a member of the triazole-containing class of pesticides. Although conazoles act similarly in plants (fungi) by inhibiting ergosterol biosynthesis, there is not necessarily a relationship between their pesticidal activity and their mechanism of toxicity in mammals. Structural similarities do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same, or essentially the same, sequence of major biochemical events. In conazoles, however, a variable pattern of toxicological responses is found; some are hepatotoxic and hepatocarcinogenic in mice. Some induce thyroid tumors in rats. Some induce developmental, reproductive, and neurological effects in rodents. Furthermore, the conazoles produce a diverse range of biochemical events including altered cholesterol levels, stress responses, and altered DNA methylation. It is not clearly understood whether these biochemical events are directly connected to their toxicological outcomes. Thus, there is currently no evidence to indicate that conazoles share common mechanisms of toxicity and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the conazoles. For information regarding EPA’s procedures for cumulating effects from

substances found to have a common mechanism of toxicity, see EPA's website at <http://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

Tetraconazole, as a triazole-derived pesticide, is one of a class of compounds that can form the common metabolite 1,2,4-triazole and two triazole conjugates (triazolylalanine and triazolylacetic acid). To support existing tolerances and to establish new tolerances for triazole-derivative pesticides, including tetraconazole, EPA conducted a human health risk assessment for exposure to 1,2,4-triazole, triazolylalanine, and triazolylacetic acid resulting from the use of all current and pending uses of any triazole-derived fungicide. The risk assessment is a highly conservative, screening-level evaluation of hazards associated with common metabolites (e.g., use of a maximum combination of uncertainty factors) and potential dietary and non-dietary exposures (i.e., high end estimates of both dietary and non-dietary exposures). In addition to the 10X interspecies factor and the 10X intraspecies factor, the Agency retained a 3X for the LOAEL to NOAEL safety factor when the reproduction study was used. In addition, the Agency retained a 10X for the lack of studies including a developmental neurotoxicity (DNT) study. The assessment includes evaluations of risks for various subgroups, including those comprised of infants and children. The Agency's complete risk assessment is found in the propiconazole reregistration docket at <http://www.regulations.gov/>, Docket Identification (ID) Number EPA-HQ-OPP-2005-0497.

An updated dietary exposure and risk analysis for the common triazole metabolites 1,2,4-triazole (T), triazolylalanine (TA), triazolylacetic acid (TAA), and triazolylpyruvic acid (TP) was completed on July 18, 2017, in association with registration requests for tetraconazole and difenoconazole fungicides. The requested new uses of tetraconazole did not significantly change the dietary exposure estimates for free triazole or

conjugated triazoles. Therefore, an updated dietary exposure analysis was not conducted. The July 18, 2017 update for triazoles may be found in docket ID number EPA-HQ-OPP-2016-0573.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There are no residual uncertainties for pre- and post-natal toxicity. There was no evidence of increased quantitative susceptibility of rat or rabbit fetuses following *in utero* exposures to tetraconazole. However, there was evidence of increased qualitative susceptibility of fetuses in the rat prenatal developmental toxicity study where there were increased incidences of supernumerary ribs, and hydroureter and hydronephrosis were seen in fetuses at the same dose that caused maternal toxicity (decreased body weight gain, and food consumption and increased water intake, and increased liver and kidney weights). In addition, there was also no evidence of increased quantitative or qualitative susceptibility to offspring in the 2-generation reproduction study.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for tetraconazole is complete.

ii. Although there were effects indicative of neurotoxicity in the acute neurotoxicity study in rats, there were no such effects noted in the subchronic neurotoxicity study or any other studies in the database. The fact that a clear NOAEL was established for the neurotoxicity effects observed and the selected endpoints are protective of those effects, which were observed at doses 2- to 100-fold higher than the most sensitive effects in the database (liver and kidney). Therefore, there is no need for a developmental neurotoxicity study or additional uncertainty factors (UFs) to account for neurotoxicity.

iii. As discussed in Unit III.D.2., there is no evidence that tetraconazole results in increased quantitative susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. There is evidence of increased qualitative susceptibility to fetuses in the rat prenatal developmental toxicity study (increased incidences of supernumerary ribs, and hydroureter and hydronephrosis). The level of concern (LOC) is low because: (1) the fetal effects were seen at the same dose as the maternal effects; (2) a clear NOAEL was established; (3) the developmental NOAEL from a study in rats is being used as the POD for the acute dietary endpoint (females 13-49 years of age) and are protected for; and (4) there were no developmental effects in the rabbit study. There is also no evidence of increased quantitative or qualitative susceptibility to offspring in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The acute dietary food exposure assessments were performed based on 100 PCT, tolerance-level residues, and modeled water estimates. Therefore, the acute analysis is highly conservative. The chronic dietary exposure analysis utilized modeled drinking water estimates, empirical processing factors, average field trial residues, average residues from the feeding studies, PCT, and modeled drinking water estimates. Therefore, the chronic risk estimates provided in this

document are unlikely to underestimate the risks posed by tetraconazole. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to tetraconazole in drinking water. These assessments will not underestimate the exposure and risks posed by tetraconazole.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to tetraconazole will occupy 4.8% of the aPAD for all infants (<1 year old), the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to tetraconazole from food and water will utilize 91% of the cPAD for all infants (<1 year old), the population group receiving the greatest exposure. There are no residential uses for tetraconazole.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). A short-term adverse effect was identified; however, tetraconazole is not registered for any use patterns that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Because there is no short-term residential exposure and chronic dietary exposure has already

been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for tetraconazole.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term adverse effect was identified; however, tetraconazole is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for tetraconazole.

5. *Aggregate cancer risk for U.S. population.* As discussed in Unit III.A., EPA has concluded that tetraconazole is "Not likely to be carcinogenic to humans at levels that do not cause increased cell proliferation in the liver." Because the chronic endpoint is protective of cell proliferation in the liver, there is not likely to be a cancer risk from exposure to tetraconazole.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to tetraconazole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate analytical methods are available to enforce the established/recommended tetraconazole plant and livestock tolerances (D280006, W. Donovan, 10-Jan-2002, D267481, 12-Oct-2000; D278236, W. Donovan, 22-Oct-2001). Isagro has also submitted adequate method validation and independent laboratory validation (ILV) data that indicates that the QuEChERS multi-residue method L00.00-115 (48135104.der) is capable of quantifying tetraconazole residues in/on a variety of fruit, cereal grain, root, oilseed, and livestock commodities.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established MRLs for tetraconazole.

C. Revisions to Petitioned-For Tolerances

Some of the terminology the petitioner used to describe requested tolerances is not the standard terminology the Agency uses for establishing tolerances. Tolerances requested for

“dried shelled pea and bean (except soybean) subgroup 6C” and “crop group 16, forage, fodder, and straw of cereal grains group” are being issued for “pea and bean, dried shelled, except soybean, subgroup 6C” and “grain, cereal, forage, fodder, and straw, group 16”, respectively. The subgroup 6C includes all edible pods and the dried and succulent seed forms of the commodities in the subgroup; the Agency does not specifically used the term “seed” in the naming of this subgroup, consistent with its food and feed commodity vocabulary. The petitioner also requested tolerances for hay and vine commodities in subgroup 6C. Hay and vine are plant parts of legume vegetables, which are covered under crop subgroup 7A. Therefore, the Agency is establishing this requested tolerance as “vegetable, foliage of legume, except soybean, subgroup 7A”.

Additionally, the Agency has determined that some of the field trials were replicates, which lead to the agency recommending for different tolerance levels than that proposed. EPA added significant figures for the tolerance values to be consistent with its practice.

Although the petitioner requested tolerances for residues of tetraconazole in or on commodities in group 16 except corn, the tolerances for corn, field, forage and corn, field, stover as well as corn, pop, stover are superseded by the new group 16 tolerances. Based on cereal grain processing data, which indicate that tetraconazole residues concentrate in the processed commodities of barley and wheat, the Agency is establishing tolerances for residues in or on the flour and bran commodities of barley and the flour, bran, and germ commodities of wheat. In addition, because residue data indicate that there will be increased residues in aspirated grain fractions as a result of the use of tetraconazole on cereal grains, the Agency is modifying the existing tolerance for aspirated grain fractions, in accordance with the provisions at 40 CFR 180.40(f)(1)(i)(B).

Finally, because the established tolerances will increase the ruminant dietary burdens, the Agency is increasing existing milk and meat tolerance levels as well, pursuant to 40 CFR 180.6(b).

V. Conclusion

Therefore, tolerances are established for residues of tetraconazole, 1-[2-(2,4-dichlorophenyl)-3-(1,1,2,2-tetrafluoroethoxy)propyl]-1*H*-1,2,4-triazole, in or on pea and bean, dried shelled (except soybean) subgroup 6C at 0.09 ppm; vegetable, foliage of legume (except soybeans) subgroup 7A at 8.0 ppm; barley, grain at 0.30 ppm; rapeseed subgroup 20A at 0.90 ppm; wheat, grain at 0.05 ppm; wheat, germ at 0.50 ppm; grain, cereal, forage, fodder, and straw, group 16 at 7.0 ppm; barley, bran at 1.0 ppm; barley, flour at 0.50 ppm; wheat, bran at 0.15 ppm; wheat, flour at 0.08 ppm. In addition, EPA is revising existing tolerances for grain, aspirated fractions to 4.0 ppm; milk to 0.06 ppm; cattle, meat to 0.02 ppm; goat, meat to 0.02 ppm; horse, meat to 0.02 ppm; and sheep, meat to 0.02 ppm. Additionally, the existing tolerances for corn, field, forage; corn, field, stover; and corn, pop, stover are being removed since they are superseded by this action.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001); Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997); or Executive Order

13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 4, 2018.

Donna Davis,

Acting Director, Registration Division, Office of Pesticide Program.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.557; in the table to paragraph (a):

- a. Remove the entry for “Aspirated grain fractions”;
- b. Add alphabetically entries for “Barley, bran”; “Barley, flour”; and “Barley, grain”;
- c. Revise the entry for “Cattle, meat”;
- d. Remove the entries for “Corn, field, forage”; “Corn, field, stover”; and “Corn, pop, stover”;
- e. Add alphabetically entries for “Grain, aspirated fractions”; “Grain, cereal, forage, fodder, and straw, group 16”;
- f. Revise the entries for “Goat, meat”; “Horse, meat”; “Milk”;
- g. Add alphabetically entries for “Pea and bean, dried shelled (except soybean) subgroup 6C”; “Rapeseed subgroup 20A”;
- h. Revise the entry for “Sheep, meat”; and
- i. Add alphabetically entries for “Vegetable, foliage of legume (except soybeans) subgroup 7A”; “Wheat, bran”; “Wheat, flour”; “Wheat, germ”; and “Wheat, grain”.

The additions and revisions read as follows:

§ 180.557 Tetraconazole; tolerances for residues.

(a) * * *

Commodity	Parts per million
Barley, bran	1.0
Barley, flour	0.50
Barley, grain	0.30
* * *	* * *

Cattle, meat	0.02
* * *	* * *
Goat, meat	0.02
Grain, aspirated fractions	4.0
Grain, cereal, forage, fodder, and straw, group 16	7.0
* * *	* * *
Horse, meat	0.02
* * *	* * *
Milk	0.06
* * *	* * *
Pea and bean, dried shelled (except soybean) subgroup 6C	0.09
* * *	* * *
Rapeseed subgroup 20A	0.90
* * *	* * *
Sheep, meat	0.02
* * *	* * *
Vegetable, foliage of legume (except soybeans) subgroup 7A	8.0
* * *	* * *
Wheat, bran	0.15
Wheat, flour	0.08
Wheat, germ	0.50
Wheat, grain	0.05

* * * * *